Journal of Orthopaedic Trauma Publish Ahead of Print
DOI: 10.1097/BOT.0000000000000929

Treatment approach for infection of healed fractures after internal fixation

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Conflict of Interest and Source of Funding: All authors state there are no financial, consultant or institutional conflicts of interests, or other relationships that might lead to bias. There was no source of funding for this work.

Presented in part at the Annual Meeting of the Orthopaedic Trauma Association, San Diego, CA, October 2015.

ABSTRACT

Objective: To review the efficacy of a treatment approach for patients with infection and colonized implants after open reduction and internal fixation of fractures.

Design: Retrospective case series.

Setting: Level one trauma center.

Patients: Twenty patients were treated for wound infection with colonized implants after open reduction and internal fixation.

Intervention: Surgical debridement, removal of implants and a short post-operative oral antibiotic course.

Main Outcome Measurement: The course of patients after surgical debridement and removal of implants, including culture results, antibiotic administration and presence of recurrent clinical infection and radiographic union.

Results: Twenty patients had clinical presentations including skin breakdown, serous drainage, purulent drainage and/or exposed implants, most commonly of the tibia (15 of 20). Mean time from index procedure to debridement with implant removal was 19.7 months. At time of debridement and implant removal, 18 of 20 (90%) patients had a positive intraoperative culture (16 routine cultures, 2 broth cultures). The most common bacteria were Enterobacter cloacae (5/17) and methicillin sensitive Staphylococcus aureus (MSSA) (4/17). All patients had soft tissue healing without signs of recurrent infection after mean follow up of 40 months after implant removal.

Conclusions: Surgical debridement with implant removal plus a short oral antibiotic course is effective to resolve wound infection with a colonized implant in the setting of healed fracture after internal fixation.

Key Words: wound, infection, colonized implant, bacteria

Level of Evidence: Therapeutic Level IV.

INTRODUCTION

Wound infection is a common yet potentially serious complication after internal fixation of fractures[1–5]. Depending on status of fracture healing and the extent and chronicity of symptoms, management recommendations may vary[6]. In many clinical scenarios in

orthopaedic surgery, experts have sought to develop standardized treatment algorithms for infection, such as prosthetic joint infection[7], early postoperative infections after internal fixation[3,8] and septic nonunion[9]. Nevertheless, there remain clinical scenarios that lack evidence-based management recommendations as a result of a paucity of literature available to aid in decision-making.

When evaluating infection after internal fixation, it is important to distinguish acuity of infection and status of fracture healing when applying treatment algorithms. For acute post-operative infection (within several weeks after internal fixation), surgical debridement with retention of the implant coupled with appropriate oral or intravenous antibiotics until fracture union occurs is considered standard of care[3,8]. For septic nonunion, treatment must address both infection and mechanical instability of the fracture. This may be performed in a single-stage or multiple-stage fashion, depending on type of fracture and extent of infection[9–11]. In chronic diffuse osteomyelitis, radiographs will often demonstrate bony erosion and/or lucency, revealing implant loosening due to permeative infection of the bone, and bony debridement and intravenous antibiotics are warranted, followed by reconstruction[12–14]. However, in a subset of patients who present with superficial wound infection and healed fractures after internal fixation, the treatment algorithm is less clear. These patients may present with elevated or even normal inflammatory labs, yet with persistent insufficient soft tissue healing, often accompanied by drainage, and a presumed colonized implant. In effort to encourage wound healing, surgeons have employed a variety of treatment approaches, including observation and local wound care, oral versus intravenous antibiotics, or even a return trip to the operating

room for irrigation and debridement with or without implant removal. Intraoperatively, if positive cultures are obtained, should the implant be retained or removed?

Anecdotally, this clinical scenario is not uncommon, though there is limited evidence in the literature describing the management of this set of patients. We have observed these patients may receive several week courses of intravenous antibiotics and/or repeat debridements in the operating room, at the discretion of the treating surgeon, potentially with the consultation of infectious disease specialists. Through experience, we propose that a simpler treatment approach consisting of implant removal and a short course of oral antibiotics is sufficient to achieve wound healing, and to eradicate infection in a cost-effective manner, that is without a several week course of intravenous antibiotics. Thus, the purposes of this paper are to describe the management and to review the clinical outcomes of a series of patients with this specific presentation.

PATIENTS AND METHODS

We conducted a retrospective chart review of one fellowship trained trauma surgeon's practice from 2007-2015 at a single level one trauma center identifying 20 patients who presented with a superficial wound infection and/or insufficient superficial wound healing with a colonized implant and radiographically healed fractures after internal fixation. Patients with acute presentation of infection within two to four weeks after fixation and non-united fracture were excluded. Patients with longstanding fracture nonunion and infection, or with chronic diffuse osteomyelitis were also excluded. Electronic medical records and radiographs of eligible adult patients were reviewed.

Demographic data, medical comorbidities, injury features, and treatments were recorded. Laboratory data included white blood cell count, erythrocyte sedimentation rate and C-reactive protein. Radiographs were reviewed to document fracture healing and implant integrity.

All patients underwent surgical irrigation and debridement with implant removal. Surgical debridement consisted of removal of any nonviable soft tissue, followed by gravity flow irrigation with normal saline. Implants were noted to be well-fixed, and fractures were united in all cases as confirmed with postoperative radiographs. Intraoperative cultures were routinely taken in 18 of 20 patients from deep soft tissue and bone around the location of prior implants, and samples were incubated in both aerobic and anaerobic culture media for seven days. Wounds were primarily closed in all but one patient (#4), who required a gracilis muscle flap. All patients received one or three doses of routine perioperative intravenous antibiotics, depending on if they underwent outpatient surgery (one dose) or were admitted overnight (three doses). Patients with a positive intraoperative culture received a short course of oral antibiotics based on culture results (median 14 days; range, 7 to 24 days) and were allowed weight bearing as tolerated, post-operatively. No patients received long term intravenous antibiotics. Our primary outcome measure was a clinically healed wound at final follow-up, as reported from either the senior surgeon's clinical note and/or documented telephone encounter for patients who did not return to clinic.

RESULTS

Summarized demographic data of the study patients can be found in Table 1, and patient specific data can be found in Table 2. Twenty patients, including 19 males and 1 female, were considered to have an infection with insufficient soft tissue healing over a healed fracture after internal fixation. Mean patient age was 46.5 years (standard deviation (SD), 13.4 years, and range, 26 to 65), and mean patient body mass index (BMI) was 27.3 (SD, 6.5). Three patients were diabetic (15%), and 15 current or former smokers (75%). Clinical presentation of the involved wound included serous drainage (9), purulent drainage (5), exposed implant (4) or wound breakdown/dehiscence (2). Most initial injuries were closed fractures (55%), with the majority occurring in the tibia (70%). Mean time from index procedure to debridement with implant removal was 19.7 months (range, 3 to 98 months). The implants removed were a plate and screws in 18 of 20 patients, and an intramedullary nail in two patients. Mean pre-operative inflammatory marker levels for white blood cell count (WBC), erythrocyte sedimentation rate (ESR) and C-Reactive protein (CRP), were 9.0 (SD 2.5) [normal reference 4.5-11.5], 19.6 (SD 10.2) [normal reference <15], and 1.0 (SD 0.7) [normal reference <0.8], respectively.

At the time of surgical debridement and implant removal, 18 of 20 (90%) patients had a positive culture, with two in supplemented broth culture only. Of the two patients without positive cultures, neither had intraoperative cultures sent. Intraoperative culture results can be found in Table 3. The most common bacteria resulted were Enterobacter cloacae in 29% (5/17) of patients, and methicillin sensitive Staphylococcus aureus in 23% (4/17) of patients. A summary of culture results and antibiotic treatment can be found in Table

2. Antibiotic treatment consisted of a short post-operative oral course with median duration of 14 days, ranging from seven to 24 days. After implant removal, all 20 patients demonstrated clinical evidence of complete wound healing without signs of recurrent infection (mean follow up of 39.6 months) or need for further surgical intervention. Additionally, all 20 patients maintained satisfactory fracture alignment and union on post-operative radiographs.

DISCUSSION

Infection after internal fixation of fractures is common, and can be a challenging and costly complication to manage. We report a series of patients considered to have a wound infection with a colonized implant over a healed fracture after internal fixation. Patients were managed with surgical debridement and implant removal with post-operative oral antibiotics, and demonstrated soft tissue healing with no evidence of recurrent infection almost 40 months after implant removal.

The orthopaedic literature offers varied recommendations on how to treat infection after internal fixation of fractures. When the fracture has yet to achieve union, such as in the case of wound infection in the early post-operative period, the patient can be treated with implant retention, debridement and antibiotics, to allow time for the fracture to heal[3,8]. It is important to note that nine patients in our series were not yet radiographically healed when they initially presented with insufficiently healed wounds. These patients were followed by the senior surgeon for an average of four months (range, one to nine) to ensure fractures were healed on radiographs prior to implant removal. During this time,

these patients were not placed on antibiotics, and their wounds were managed with local wound care. In all cases, once patients demonstrated radiographic union, surgical debridement and implant removal was recommended to encourage wound healing. In the case of chronic osteomyelitis with or without nonunion, treatment must address the mechanical instability of the fracture in addition to routinely prescribed long courses of intravenous antibiotics[12–14]. However, in the case of infection in healed fractures after internal fixation, the literature is scant.

In 1993, Law Jr. et al reported a series of nine patients who presented with late infection in healed fractures presenting from 15 months to 19 years after fixation[15]. They report all patients had clinically healed wounds six months after surgical debridement and removal of implants. It is widely known the polysaccharide glycocalyx promotes bacterial adherence to metal implants over time (generally >4 weeks) creating a biofilm. Upon maturation, it is thought these bacteria participate in "quorum sensing" communication and through gene expression can increase virulence to resist the host immune response and antibiotic therapy[16–18]. The rationale for the removal of implants is that it eliminates this avascular reservoir for bacterial colonization without compromising mechanical stability in already healed fractures[19]. Unlike the patients in our series, all of the patients in the Law Jr. et al series demonstrated radiographic evidence of bone resorption or implant loosening, indicating chronic diffuse osteomyelitis, and lending support to their use of long-term intravenous antibiotics post-operatively. When diffuse osteomyelitis is not suspected, as in our series, complete wound healing can be achieved with removal of implants and a short course of oral antibiotics, even amidst positive intraoperative

cultures. It our clinical sense that antibiotics likely play a secondary role to the removal of implants in preventing recurrence or progression to chronic osteomyelitis, and that in such cases long term intravenous antibiotics are unnecessary. To our knowledge, no prior studies have compared the efficacy of intravenous versus oral antibiotics to treat infection in the setting of healed fractures after internal fixation.

Furthermore, as in the case of some of the patients in our series, signs of clinical infection are less pronounced and inflammatory markers are normal, while intra-operative cultures are positive. In our series, 18 of 18 patients in whom intraoperative cultures were taken had a positive result. Gram-negative rods and/or Staphylococcus aureus grew in 16 of the 18 patients, which is similar to the recent large series by Torbert et al. in 2015, identifying these organisms as frequently found in post-operative infections after internal fixation of fractures and as unlikely contaminants[20].

Recent reports have encouraged an aggressive approach to the treatment of intraoperative wound cultures after internal fixation. A 2016 multicenter series revealed a 20% rate (91/453) of surprise positive intra-operative cultures during elective nonunion surgery, despite negative inflammatory markers and no signs of clinical infection pre-operatively[21]. They recommended all patients with positive cultures be treated with intravenous antibiotics, because the benefit of preventing one chronic infection outweighed the risks of being on antibiotics. In addition, another 2016 multicenter series comparing culture-positive and culture-negative infections after internal fixation concluded both groups were not different in regards to treatment failure (number of

repeat procedures needed, and time to union), and recommended patients with negative cultures be treated no differently than patients with positive cultures in regards to duration and route of antibiotics[4]. Intravenous antibiotics alone were used in 60% of patients, though they did not draw any comparison to treatment with oral antibiotics. In light of these studies, the results of our series further emphasize the importance in understanding clinical context when deciding appropriate surgical and antibiotic treatment. Nevertheless, treatment decision-making for positive intra-operative cultures is not straight forward, and must take into account the clinical setting (+/- signs of infection, +/- elevated inflammatory markers). Often times it warrants the consultation of infectious disease specialists, particularly if bacteria are considered to be possible contaminants.

Therefore, given the lack of evidence regarding this problem, and the current medicolegal culture in the United States that encourages defensive medicine, it is not unreasonable to assume in the community at large, many similar patients may be treated unnecessarily with long courses of intravenous antibiotics. In addition, the potential risks of prolonged intravenous catheters are not inconsequential, and include but are not limited to line sepsis, phlebitis, drug abuse, thrombosis, and mechanical failure[22,23]. Judicious antibiotic usage will also minimize adverse drug effects for patients as well as development of resistant organisms[24]. In addition to the physical burden long term intravenous therapy may have on patients, there is a significant economic cost to the health system[25]. For instance, in the case of methicillin resistant staphylococcus aureus, data from our institution reveals 2015 cumulative costs for a peripherally inserted central catheter line placement, six weeks of intravenous vancomycin and home nursing care can cost

upwards of $12,716, compared to two weeks of oral trimethoprim-sulfamethoxazole that costs $14. Other estimates of costs for stay for intravenous antibiotics are up to $1,196 per day in the hospital and $811 per day at a skilled nursing facility[26–29] or $50,232 and $34,062, respectively after six weeks.

Though our series is too small to perform statistical analysis, it is important to note the negative impact patient risk factors can have on the healing process of wounds after internal fixation. Non-modifiable risk factors include tibia fractures and open fractures, which is consistent with previous studies[30,31]. A recent analysis of Nationwide Inpatient Sample data revealed tibia fractures as an independent predictor of infection-related implant removal[30]. Though our series had a near even distribution of closed versus open fractures (11 versus nine, respectively), it is well known reducing the risk of future infection due to the open nature of a fracture takes place during its initial management with early antibiotic administration[32] and surgical debridement[26]. Modifiable risk factors include smoking, diabetes and nutritional status. The ischemic effect of smoking on local tissues is well reported, though modifiable with cessation, which makes patient counseling and education worthwhile throughout the treatment course[6,15,33–35]. As well, close glycemic control in diabetics and the assessment and treatment of nutritional status with supplementation should be considered in all patients with a poor healing wound as a measure to improve the host immune response[6,30,36,37].

The small sample size and lack of a control group in our study precludes meaningful statistical analysis, and we recognize this as a limitation. Second, we ideally would have

complete laboratory data for all patients pre-operatively, which was incomplete in seven patients, and intra-operative cultures that were not taken in two patients. Nevertheless, this series serves as a treatment strategy for what we believe to be a common clinical scenario in orthopaedic surgery. Surgical debridement with implant removal plus a short oral antibiotic course appears sufficient to foster soft tissue healing and to prevent recurrence of infection in the setting of wound infection with a colonized implant and healed fracture after internal fixation. We propose that intravenous antibiotics are not necessary to eradicate the infection in such cases, one the infected implant has been removed.

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TABLE 1. Demographic data

Total Patients	20	
Male	19	
Female	1	
Mean age, years	46.5 (26-65)	
Mean BMI	27.3	
Diabetes mellitus	3	
Smoking status		
Current	10	
Former	5	
Never	5	
Main presenting clinical symptoms		
Serous drainage	9	
Purulent drainage	5	
Visible implants	4	
Skin breakdown	2	
Mean Pre-Revision Surgery Lab Values [normal reference]		
WBC	9.0	[4.5-11.5]
ESR	19.6	[0-15]
CRP	1.0	[0-0.8]

BMI=body mass index; WBC=white blood cell count; ESR=erythrocyte sedimentation rate; CRP=C-reactive protein.

TABLE 2. Patient specific demographics, culture results and treatment

*Time from index procedure to revision procedure; **Time from revision procedure to most recent clinical documentation of local infection recurrence;

Patient	Demographics					Open versus Closed Fracture	Injury Fracture	Presentation		Labs			Intra-op Culture	Antibiotic Treatment	Follow Up (mo)**
	Age	Sex	BMI	DM	Smoking			Symptoms	Time (mo)*	WBC	ESR	CRP			
1	65	M	29	-	Never	Closed	Tibial plateau	Purulence	8.7	6.6	-	0.5	Enterobacter cloacae	PO Augmentin x2 wks	43.6
2	65	M	25.1	-	Former	Closed	Tibial plateau and shaft	Serous drainage	19.7	-	-	-	Enterobacter cloacae	PO Ciprofloxacin x2 wks	45.2
3	56	M	28.7	-	Former	Open	Tibial shaft	Purulence	15.9	8.4	-	-	Pseudomonas aeruginosa	PO Ciprofloxacin x2 wks	61.9
4	61	M	26.7	-	Never	Open	Tibial plafond	Visible hardware	20.8	10.1	23	1.1	MRSA	PO Bactrim x2 wks	25.7
5	29	M	21.3	-	Current	Open	Distal tibial shaft	Purulence	17.0	15.2	17	0.9	Psuedomonas aeruginosa, MSSA	PO Ciprofloxacin x10 days	55.0
6	58	M	26.1	-	Current	Closed	Humeral shaft	Serous drainage	20.1	5.9	1	2.6	Pseudomonas aeruginosa	PO Augmentin x4 wks	31.2
7	26	M	21.9	-	Never	Open	Femoral shaft	Serous drainage	14.6	14.6	-	-	Enterococcus faecalis, MSSA	PO Augmentin and Bactrim x3 wks	36.0
8	52	M	25.8	-	Current	Open	Femoral shaft	Purulence	74.3	8.4	19	2.7	MSSA	PO Dicloxacillin x2 wks	20.2
9	38	M	46	-	Former	Closed	Proximal tibial shaft	Visible hardware	8.3	7	22	0.5	MSSA	PO Clindamycin x10 days and PO Bactrim x2 wks	55.6
10	55	M	28	-	Former	Closed	Distal tibial shaft and fibula	Purulence	5.9	9	37	1	MSSA	PO Clindamycin x10 days and PO Bactrim, total 3 wks	90.4
11	26	M	19.5	-	Current	Closed	Proximal humerus	Serous drainage	15.6	8.7	22	0.8	Enterobacter cloacae	PO Ciprofloxacin x2 wks	10.7
12	27	M	31.1	-	Current	Open	Distal tibial shaft	Serous drainage	8.3	10.2	18	0.9	Enterobacter cloacae	PO Ciprofloxacin x2 wks	14.8
13	34	M	20.3	-	Current	Open	Distal tibial shaft	Serous drainage	6.2	9.7	23	0.6	MSSA	PO Dicloxacillin x10 days	12.0
14	45	M	28.6	-	Never	Closed	Olecranon	Serous drainage	5.2	-	-	-	MRSA	PO Clindamycin x2 wks	95.8
15	55	M	23.7	-	Former	Open	Distal tibial shaft	Skin breakdown	25.3	-	-	-	Streptococcus constellatus (broth)	PO Clindamycin x1 wk	50.1
16	50	M	41.6	+	Never	Closed	Tibial plateau	Serous drainage	9.7	6.2	4	0.7	Pseudomonas aeruginosa and MRSA (both broth)	PO Augmentin x1 wk, PO Ciprofloxacin x 3 wks	16.2
17	62	F	31.3	+	Current	Closed	Ankle	Skin breakdown	3.1	7.3	37	1	No cultures	No antibiotics	30.0
18	51	M	27.2	-	Current	Closed	Tibial plafond	Skin breakdown	5.5	9.9	-	-	Peptostreptococcus anaerobius, CNS	PO Augmentin x10 days	66.8
19	30	M	24.1	-	Current	Closed	Distal tibial shaft	Visible hardware	98.2	8.4	9	0.5	No cultures	PO Augmentin x10 days	22.1
20	45	M	19.7	+	Current	Open	Tibial plateau	Serous drainage	11.5	7.8	23	1	Enterobacter cloacae	PO Ciprofloxacin x2 wks	8.0

M=male; BMI=body mass index; DM=diabetes mellitus; mo=month; PO=oral; wk=weeks; WBC=white blood cell count; ESR=erythrocyte sedimentation rate; CRP=C-Reactive protein; MSSA=methicillin-sensitive staphylococcus aureus; MRSA=methicillin-resistant staphylococcus aureus. All patients were treated with plate and screws in index procedure, except patients 7 and 8 who were treated with intramedullary nail.

TABLE 3. Intraoperative Culture Bacteria

Type of Bacteria	Number of Patients
Enterobacter cloacae	5
MSSA	4
MRSA	2
Pseudomonas aeruginosa	2
Pseudomonas aeruginosa and MRSA	1
Pseudomonas aeruginosa and MSSA	1
Enterococcus faecalis and MSSA	1
Peptostreptococcus anaerobius and CNS	1
Streptococcus constellatus	1

MSSA=methicillin-sensitive staphylococcus aureus; MRSA=methicillin-resistant staphylococcus aureus; CNS=coagulase negative staphylococcus